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(54) **VALVE SYSTEM AND METHOD WITH MULTI-DIRECTIONAL PUMPING**

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A61M 5/142 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 27/006*** (2013.01); ***A61M 5/1428*** (2013.01)

(58) **Field of Classification Search**
CPC A61M 27/00; A61M 27/006; A61M 2027/004; A61M 5/1428
USPC 604/8, 9
See application file for complete search history.

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(57) **ABSTRACT**

An implantable valve system and method of using same, including a housing with a resilient membrane defining a reservoir in fluid communication with at least two ports, and at least a first set of opposing sealing features disposed on upper and lower surfaces within the housing. The membrane is capable of being depressed by a human finger to bring the sealing features together to substantially restrict fluid from passing through at least one of one of the ports, and is capable of being depressed additionally by a rolling motion of the finger to drive fluid through the other of the ports.

6 Claims, 2 Drawing Sheets

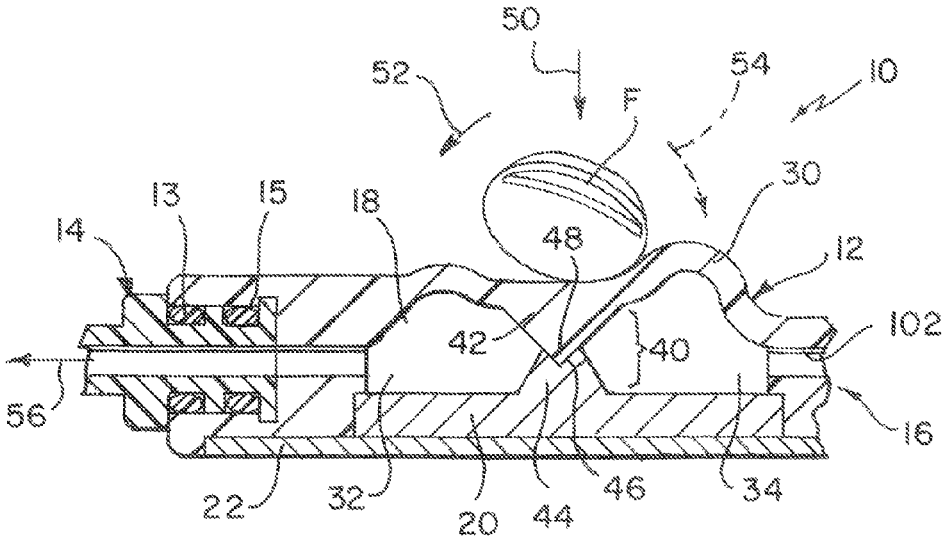


FIG. 1

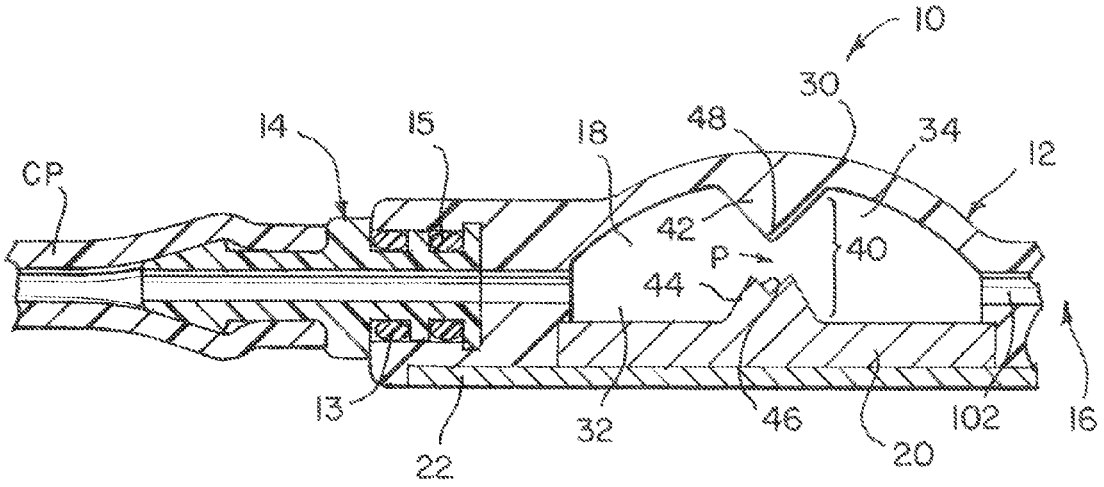
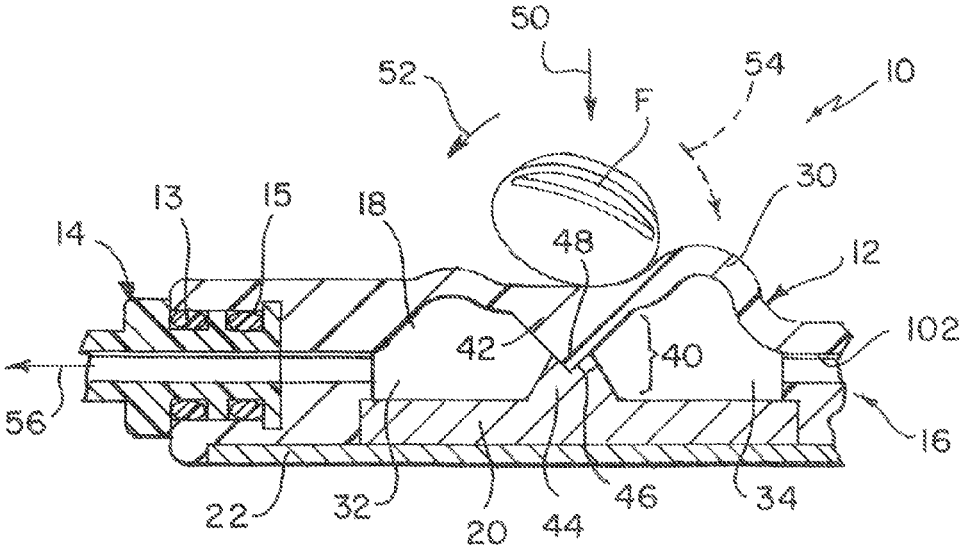

10
30
14
15
18
48
34
12
CP
42
P
40
44
13
32
46
102
16
22
20

FIG. 2


50
52
54
10
F
30
13
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18
14
48
12
42
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102
56
16
22
32
20
44
46
34

FIG. 3

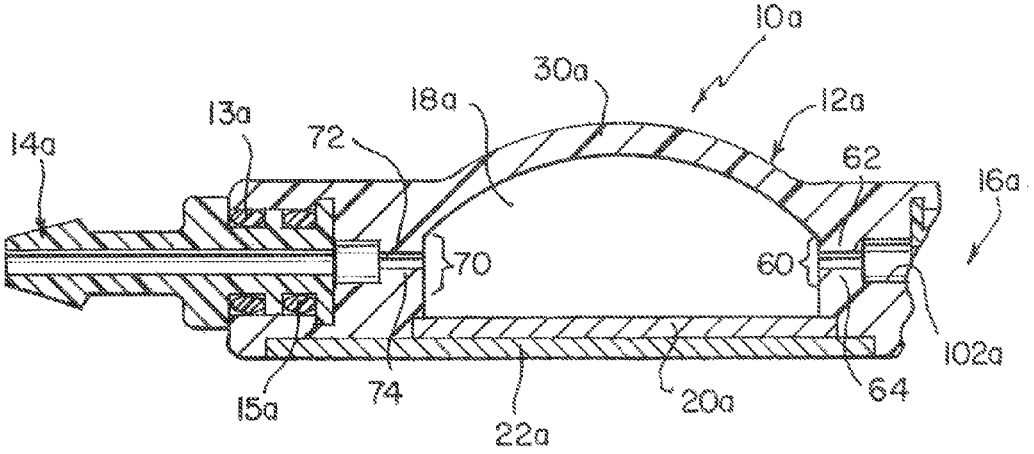
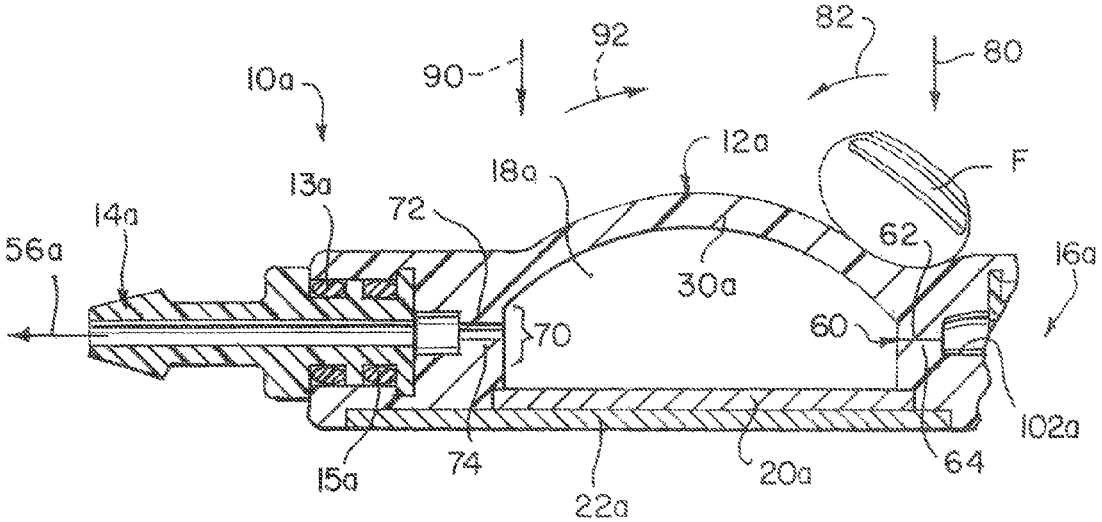

10a
30a
18a
12a
13a
72
14a
62
16a
70
60
102a
15a
74
22a
20a
64

FIG. 4


82
92
80
90
10a
12a
18a
F
13a
72
14a
62
56a
30a
16a
70
60
102a
15a
74
22a
20a
64

VALVE SYSTEM AND METHOD WITH MULTI-DIRECTIONAL PUMPING

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to clearing obstructions from implanted catheters and more particularly to a hydrocephalus valve which can be manually pumped to flush attached catheters.

2. Description of the Related Art

There are a number of treatments for medical conditions which require fluid to be removed from an organ or tissue of a patient. One such condition is hydrocephalus, where cerebrospinal fluid abnormally accumulates in the skull faster than it is withdrawn by the body. The excessive build-up of cerebrospinal fluid compresses brain tissues, which eventually leads to brain damage.

Hydrocephalus is commonly treated by implanting a shunt system, typically including a ventricular catheter in fluid communication with a ventricle within the brain, to withdraw cerebrospinal fluid at a desired rate. The rate of withdrawal of cerebrospinal fluid is usually controlled by a valve, located in a housing disposed between the ventricular catheter and a drainage catheter, having one or more pressure settings.

Complications due to obstructions within the shunt system are detailed in U.S. Pat. No. 7,094,214 by Dextradeur et al., for example. That patent discloses a multi-electrode system for clearing obstructions in a blocked catheter after a probe is inserted into a socket to energize the electrodes.

Other systems utilize a multiple finger approach whereby one finger closes a valve or blocks a catheter while a second finger pushes on the housing to pump cerebrospinal fluid from a reservoir into the blocked catheter, such as shown in U.S. Pat. No. 4,560,375 by Schulte et al. Many systems may be suited for clearing a blockage in one direction but are less suited for clearing blockages in the opposite direction.

It is therefore desirable to have an implantable valve system which enables both proximal and distal implanted catheters to be easily cleared of obstructions.

SUMMARY OF THE INVENTION

An object of the present invention is to provide an improved valve system which can be easily operated to clear an obstruction utilizing a single finger.

Another object of the present invention is to provide such a valve system which is capable of multi-directional pumping.

This invention results from the realization that an improved valve system can be manipulated utilizing a single finger to close at least a first set of opposing sealing features. The same finger is then rolled to pump fluid in a desired direction.

This invention features an implantable valve system and method of using same, including a housing with a resilient membrane defining a reservoir in fluid communication with at least two ports and having a longitudinal axis, and at least a first set of opposing sealing features disposed on upper and lower surfaces within the housing. The membrane is capable of being depressed by a human finger to bring the sealing features together to substantially restrict fluid from passing through at least one of one of the ports, and is capable of being depressed additionally by a rolling motion of the finger to drive fluid through the other of the ports.

In some embodiments, the first set of opposing sealing features is disposed transverse to the longitudinal axis of the housing. In one embodiment, the first set of opposing sealing features extends substantially perpendicularly across the reservoir to establish first and second pumping chambers when the sealing features are brought together.

In certain embodiments, one of the sealing features includes a detent and the other of the sealing features includes a recess to matingly receive the detent. In some embodiments, the housing further includes a floor portion which defines one of the sealing features.

In other embodiments, the valve system includes at least a second set of sealing features capable of substantially restricting fluid from passing through the other of the ports when the membrane is depressed in the vicinity of the second set. In some embodiments, the first set and the second set are longitudinally spaced from each other.

This invention also features a method for clearing an obstruction in one or more catheters implanted in a patient by locating a valve system implanted sub-dermally in the patient, the valve system having a housing with a resilient membrane defining a reservoir in fluid communication with at least two ports and having at least a first set of opposing sealing features disposed on upper and lower surfaces within the housing. The membrane is depressed with one finger to bring the sealing features together to substantially restrict fluid from passing through at least one of one of the ports. The finger is then moved in a rolling motion to additionally depress the membrane to drive fluid through the other of the ports to clear the obstruction.

The method may further include moving the finger in a second rolling motion in a second direction to additionally depress the membrane to drive fluid in the second direction through the one of the ports to clear a second obstruction. In some embodiments, the valve system includes at least a second set of sealing features and the method further includes, prior to moving the finger in the second rolling motion, lifting the finger after the first rolling motion and depressing the membrane with the finger to bring the second set of sealing features together.

BRIEF DESCRIPTION OF THE DRAWINGS

In what follows, preferred embodiments of the invention are explained in more detail with reference to the drawings, in which:

FIG. **1** is a schematic longitudinal cross-sectional side view of a valve system according to the present invention;

FIG. **2** is a view similar to FIG. **1** showing a single finger operating the valve system to clear an obstruction;

FIG. **3** is a schematic longitudinal cross-sectional side view of another valve system according to the present invention; and

FIG. **4** is a view similar to FIG. **3** showing a single finger operating the valve system to clear an obstruction.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

This invention may be accomplished by an implantable valve system and method of using same, including a housing with a resilient membrane defining a reservoir in fluid communication with at least two ports and having a longitudinal axis, and at least a first set of opposing sealing features disposed on upper and lower surfaces within the housing. The membrane is capable of being depressed by a human finger to bring the sealing features together to substantially restrict fluid from passing through at least one of one of the ports, and is capable of being depressed additionally by a rolling motion of the finger to drive fluid through the other of the ports.

A shunt valve system **10** is shown in axial or longitudinal side cross-section in FIGS. **1** and **2** having a shunt housing **12** and a proximal connector **14**, also referred to as a proximal port **14**, with epoxy seals **13** and **15**, shown connected to a proximal catheter CP, FIG. **1**, such as a ventricular catheter, to normally bring fluid into housing **12**. A distal port including a connector **16** connected to a distal catheter CD are not illustrated for purposes of drawing clarity. Also not illustrated are various other components such as a magnetically controllable valve unit **100** that are known to those skilled in the art, such as disclosed in U.S. Patent Publication 2012/0046595 by Wilson et al., which is incorporated herein in its entirety.

In this construction according to the present invention, a single set **40** of opposing features **42** and **44** are normally separated from each other to form a passage P within a reservoir **18** having pumping chambers **32** and **34**. Feature **44** defines a recess or groove **46** to matingly receive detent or projecting ridge **48** of feature **42**. Features **42** and **44** extend away and toward the viewer of FIGS. **1** and **2** such that pressure applied by finger F in the direction of arrow **50**, FIG. **2**, brings features **42** and **44** together to substantially restrict fluid flow there-between and to isolate chambers **32** and **34** from each other.

Housing **12** is formed of a resilient, preferably translucent, material such as silicone, at least in the region of membrane **30** to define the reservoir **18** with pumping chambers **32** and **34**. Under normal conditions, FIG. **1**, fluid passes into pumping chamber **32**, flows through set **40** into pumping chamber **34**, and then through a valve mechanism (not shown) in inlet **102**.

Feature **44** is formed on a plate **20** and is elastomeric in some constructions and substantially rigid in other constructions. Preferably, at least one of plate **20** and backing plate **20** serve as a needle guard so that needles can be inserted into reservoir **18** to sample fluids or inject liquids for medical treatment or other purposes. Plate **20** and backing plate **22** form the floor of reservoir chamber **18** in this construction.

One method according to the present invention for clearing an obstruction in one or more catheters implanted in a patient includes locating the valve system **10** by palpating the region where valve system **10** is implanted sub-dermally in the patient. The membrane **18** is depressed with one finger F, FIG. **2**, in the direction of arrow **50** to bring the sealing features **42** and **44** together to substantially restrict fluid from passing through at least port **16**. The finger is then moved in a rolling motion, in the direction of arrow **52**, to additionally depress the membrane **30** which compresses chamber **32** to drive fluid through the other of the port **14**, as illustrated by arrow **56**, to clear the obstruction in proximal catheter CP.

An obstruction in distal catheter CD can be cleared independently by instead moving the finger in a second rolling motion in a second direction, shown by dashed arrow **54**, to additionally depress the membrane to drive fluid in the second direction through the valve inlet **102** and port **16** to clear the obstruction in catheter CD.

An alternative valve system **10***a* according to the present invention is schematically illustrated in longitudinal cross-section in FIGS. **3** and **4**. Components that are similar to those of valve system **10**, FIGS. **1** and **2**, are numbered in a similar manner in FIGS. **3-4**. In this construction, valve system **10***a* defines a unitary reservoir **18***a* and includes a first set **60** of opposing features **62** and **64** and a second set **70** of opposing features **72** and **74**. A needle guard **20***a*, preferably formed of a rigid polymeric material, is secured within housing **12***a* by a backing plate **22***a*, preferably formed of silicone reinforced with a polymeric mesh, which is bonded to housing **12***a* by a medical grade epoxy.

First and second sets **60**, **70** of opposing features **62**, **64** and **72**, **74** are independently sealable by pressure exerted by finger F, FIG. **4**, in the directions and locations indicated by arrows **80** and **90**, respectively. Although they are illustrated as having substantially flat "lands" as abutting surfaces, this is not a limitation of the invention. At the location **80** of finger F as shown in FIG. **4**, features **62** and **64** are pressed together to substantially restrict fluid from flowing through inlet **102***a* and port **16***a*. Finger F is then moved in a rolling motion, in the direction of arrow **82**, to additionally depress the membrane **30***a* to drive fluid through the port **14***a*, as illustrated by arrow **56***a*, to clear the obstruction.

One technique further includes lifting the finger F after the first rolling motion and depressing the membrane with the finger F at location **90** to bring the second set **70** of sealing features **72** and **74** together. Finger F is then moved in a second rolling motion in a second direction, indicated by dashed arrow **92**, to additionally depress the membrane **30***a* to drive fluid in the second direction through the valve inlet **102***a* and port **16***a* to clear a second obstruction.

Thus, while there have been shown, described, and pointed out fundamental novel features of the invention as applied to a preferred embodiment thereof, it will be understood that various omissions, substitutions, and changes in the form and details of the devices illustrated, and in their operation, may be made by those skilled in the art without departing from the spirit and scope of the invention. For example, it is expressly intended that all combinations of those elements and/or steps that perform substantially the same function, in substantially the same way, to achieve the same results be within the scope of the invention. Substitutions of elements from one described embodiment to another are also fully intended and contemplated. It is also to be understood that the drawings are not necessarily drawn to scale, but that they are merely conceptual in nature. It is the intention, therefore, to be limited only as indicated by the scope of the claims appended hereto.

Every issued patent, pending patent application, publication, journal article, book or any other reference cited herein is each incorporated by reference in their entirety.

What is claimed is:

1. An implantable valve system comprising:

a housing with a single dome-shaped resilient membrane defining a reservoir in fluid communication with at least two ports and having a longitudinal axis;

at least a first set of opposing sealing features disposed on upper and lower surfaces within the housing, the opposing sealing features being disposed in the center region of the reservoir;

the single dome-shaped membrane capable of being depressed by a human finger to bring the sealing features together to substantially restrict fluid from passing through at least one of one of the ports and to divide the reservoir into a first pumping chamber and a second pumping chamber;

the single dome-shaped membrane further capable of being depressed additionally by a rolling motion of the finger to drive fluid through the other of the ports; and

wherein one of the sealing features includes a detent and the other of the sealing features includes a recess to matingly receive the detent.

2. The system of claim **1** wherein the first set of opposing sealing features is disposed transverse to the longitudinal axis of the housing.

3. The system of claim **1** wherein the first set of opposing sealing features extends substantially perpendicularly across the reservoir to establish first and second pumping chambers when the sealing features are brought together.

4. The system of claim 1 in which the housing further includes a floor portion which defines one of the sealing features.

5. A method for clearing an obstruction in a catheter implanted in a patient, comprising:

locating a valve system implanted sub-dermally in the patient, the valve system having a housing with a single dome-shaped resilient membrane defining a reservoir in fluid communication with at least two ports and having at least a first set of opposing sealing features disposed on upper and lower surfaces within the housing, the opposing sealing features being disposed in the center region of the reservoir;

depressing the single dome-shaped membrane with one finger to bring the sealing features together to substantially restrict fluid from passing through at least one of one of the ports and to divide the reservoir into a first pumping chamber and a second pumping chamber; and

moving the finger in a rolling motion to additionally depress the single dome-shaped membrane to drive fluid through the other of the ports to clear the obstruction.

6. A method for clearing obstructions in at least two implanted catheters, comprising:

locating a valve system implanted sub-dermally in the patient, the valve system having a housing with a single dome-shaped resilient membrane defining a reservoir in fluid communication with at least two ports and having at least a first set of opposing sealing features disposed on upper and lower surfaces within the housing, the opposing sealing features being disposed in the center region of the reservoir;

depressing the single dome-shaped membrane with one finger to bring the first set of sealing features together to substantially restrict fluid from passing through at least one of one of the ports and to divide the reservoir into a first pumping chamber and a second pumping chamber;

moving the finger in a first rolling motion in a first direction to additionally depress the single dome-shaped membrane to drive fluid in the first direction through the other of the ports to clear a first obstruction; and

moving the finger in a second rolling motion in a second direction to additionally depress the single dome-shaped membrane to drive fluid in the second direction through the one of the ports to clear a second obstruction.

* * * * *